

Appl.No.09/615,643  
Response dated January 2, 2004  
Reply to Office action of July 2, 2003

### **REMARKS**

This application was filed with 1-32 claims. Claim 20 has been previously canceled. Claims 19 and 21-31 have been previously withdrawn from consideration. Claims 1-18 and 32 have been rejected. Claims 1, 17, and 32 have been amended. Therefore, Claims 1-18 and 32 are pending in the Application. Reconsideration of the application based on the remaining claims as amended and arguments submitted below is respectfully requested.

### **Claim Rejections - 35 U.S.C. §112**

Claims 1-18, 32 have been rejected under the first paragraph of 35 U.S.C. §112 as failing to comply with the written description requirement. Specifically, the Office action states that "the implied limitation 'the binder resulting in hydration' is not supported in the specifications." Applicant would like to state that there are no implied limitations in these claims. In order to clarify the claims, Applicant has amended Claims 1 and 32 to describe the method of making the bone composite such that the bone composite will maintain a rigid form after surgical implantation. This feature is supported in the application as filed to reasonably convey to one skilled in the relevant art that the inventor had possession of the invention.

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Claim Rejections under 35 U.S.C. § 102

Claim 1 has been rejected under 35 U.S.C. §102(b) as being anticipated by Lin et al (Lin). Claims 1-3, 8-12, and 17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Dowd et al (Dowd). Claims 1-3, 10, 12, 14 and 17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Lyle. Claim 32 has been rejected under 35 U.S.C. §102(b) as being anticipated by Glimcher, et al. (Glimcher). These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicant would like to specifically define herein the term "solid structure" as a bone composite having rigid and weight bearing characteristic such that the bone composite is self supporting and is not dependent upon another object to provide shape or structural form.

In regard to claim 1, Claim 1 has been amended so that the bone tissue is osteoinductive ground bone tissue in particle form and the bone composite is cured into a self-support, solid structure that will maintain a rigid form before and after surgical implantation. None of the cited prior art have these features.

Lin teaches a biodegradable binder of the type that does not contain osteoinductive particles. Lin also requires the bone implant material to be moldable to be applied to a bone site (Column 3, lines 15-23). Also, the roll or block form described by Lin is a delivery method and not a structural form for the implantation

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of the Lin material. Lin teaches a biodegradable binder to form the material into a hand moldable mass. The current invention teaches a solid rigid form. Lin also teaches away from using osteoinductive bone material. Specifically the preferred filler disclosed in Lin, hydroxyapatite, is a hard biocompatible filler that does not contain the osteoinductive proteins found in osteoinductive ground bone tissue.

Dowd et al. specifically requires the shaped material, even after any drying period, to become "flexible and pliable when wetted or hydrated" (Column 5, lines 23-25 and 29-35).

Lyle does not teach a self-supporting solid structure that will maintain rigid form before and after surgical implantation. Lyle is a coating. At best, Lyle is dependent upon the medium to which it is applied for structural integrity and support. Lyle does not show a composite with rigid and weight bearing characteristic that is self supporting and is not dependent upon another object to provide shape or structural form. This effectively eliminates the use of a coating made of bone material as a "solid structure". Lyle requires a prosthetic implant in which to apply the powered bone coating. The prosthetic implant gives Lyle structure, not the bone coating. Lyle does not teach osteoinductive ground bone tissue in particle form or molding the osteoinductive ground bone tissue into a bone composite.

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In regard to Claim 32, Claim 32 has been amended so that the bone composite solidifies into a self-supporting, force bearing solid structure that will maintain a rigid form before and after surgical implantation. Glimcher, like Lyle, is used as a coating. The Glimcher patent cannot support force loads and is used as a spray and uses "other materials to serve as structural supports until the crystals (of Glimcher) are replaced by newly formed bone", column 11, lines 64-66. Also, Glimcher cannot inherently anticipate unless it is clear that "the missing descriptive matter (solidification after application) is necessarily present in the thing described in the reference (Glimcher)," and inherency "may not be established by probabilities and possibilities." *Continental Can Co. USA v. Monsanto Co.*, 948 F2d 1264, 1269 (Fed. Cir 1991). Glimcher does not purport to solidify or to maintain solidification after implantation.

In regard to Claims 2-18, Claims 2-18 are dependent on Claim 1, and include features not anticipated by the prior art. As such, Claims 2-18 are patentable.

Thus, Applicant respectfully requests that the rejection of Claims 1-18 and 32 under 35 U.S.C. §102(b) be withdrawn.

#### Claim Rejections - 35 U.S.C. §103

Claims 4-7 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dowd et al. Claim 13 has been rejected under 35 U.S.C. § 103(a) as being

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unpatentable over Lyle in view of Bonutti. Claims 15 and 16 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lyle. Claim 18 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dowd et al. in view of Bonutti.

Claims 4-7, 13 15, 16, and 18 are dependent on Claim 1, and include features not shown in the prior art. As such, Claims 4-7, 13 15, 16, and 18 are patentable. Thus, Applicant respectfully requests that the rejection of Claims 4-7, 13 15, 16, and 18 under 35 U.S.C. §103(a) be withdrawn

Applicant would like to note that support for the amendments to the claims as made herein can be found in the originally filed specification. For example, on pages 2-7, the specification specifically addresses prior art bone implants that “usually lack[s] sufficient structural strength and density” (page 7 lines 9-10) and state that the current invention addresses these problems. The current invention is also described as being capable of forming many structural shapes and forms including useable implants, bone prostheses, pins, screws, plates, discs, and the like for use in surgery. To one skilled in the art, these shapes necessarily are self supporting and maintain a rigid form during surgery. Also, it is stated that the binder “can be used in skeletal repair and revision[s] methods without the ground bone coming apart.” (page 10-11, lines 19-1)

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Applicant has commented on some of the distinctions between the cited references and the claims to facilitate a better understanding of the present invention. This discussion is not exhaustive of the facets of the invention, and Applicant hereby reserves the right to present additional distinctions as appropriate. Furthermore, while these remarks may employ shortened, more specific, or variant descriptions of some of the claim language, Applicant respectfully notes that these remarks are not to be used to create implied limitations in the claims and only the actual wording of the claims should be considered against these references.

The Commissioner is authorized to charge any deficiency or credit any overpayment associated with the filing of this Amendment and Response to Deposit Account 23-0035.

Respectfully submitted,



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